

**Amendments to the Specification:**

**Please replace paragraph [0023] with the following amended paragraph:**

This is done by packaging the product in a pouch that provides a barrier to atmospheric oxygen and also maintains a sterile environment, and that optionally comprises an oxygen absorber. The latter, although not essential, helps to maintain the reduced level of oxygen. A preferred pouch may be made, for example, of a first layer comprising a material such as 12 $\mu$  PET, 25.4 $\mu$  WPE/Foil/Adhesive and 50 $\mu$  Clear EZ PEEL® Peel® material; a second layer comprising a material such as 2FS Uncoated TYVEK® Tyvek® material, porosity 18-240 seconds by the Gurley porosimeter test (100 cc of air to pass through 1 square inch of TYVEK® Tyvek® material); and a third layer comprising a material such as 12 $\mu$  PET, 25.4 $\mu$  WPE/Foil/Adhesive and 50 $\mu$  Clear EZ PEEL® Peel® material (a fully coextruded, nylon-core top web system available from Perfecseal Ltd., Springfield Industrial Estate, Londonderry, BT48 0LY, Northern Ireland, UK); wherein the second layer is between the first and third layer. TYVEK® material is commercially available from DuPont and consists of multiple spun woven extruded polyethylene strands, compressed under high pressure to form a complex system of microscopic porous channel which provides a tortuous path within a thin flexible opaque sheet. An alternative pouch comprising two layers of material such as 12 $\mu$  PET, 25.4 $\mu$  WPE/Foil/Adhesive and 50 $\mu$  Clear EZ PEEL® Peel® may be used with the present invention when, for example, the oxygen absorber is not used.

**Please replace paragraph [0030] with the following amended paragraph:**

A pouch was made of a first layer comprising 12 $\mu$  PET, 25.4 $\mu$  WPE/Foil/Adhesive and 50 $\mu$  Clear EZ PEEL® Peel® material; a second layer comprising 2FS Uncoated TYVEK® Tyvek® material, porosity 18-240 seconds by the Gurley porosimeter test (100 cc of air to pass through 1 square inch of TYVEK® Tyvek® material); and a third layer comprising 12 $\mu$  PET, 25.4 $\mu$  WPE/Foil/Adhesive and 50 $\mu$  Clear EZ PEEL® Peel® material; wherein the second layer was between the first and third layers.

**Please replace paragraph [0032] with the following amended paragraph:**

These settings were found to give % oxygen levels between 5 and 11%. For comparison, samples were also packaged in standard TYVEK® Tyvek® material EtO pouches (these packages do not provide an Oxygen barrier) and irradiated at the E-beam dose level mentioned below. The impact of sterilisation process on the mechanical properties of the balloons was evaluated by measuring the pressure required to burst the balloons.